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Dated: January 28, 2010

Signature: Jeanne M. Brashear/56,301  
(Jeanne M. Brashear)

Docket No.: 328967/34891.1  
(PATENT)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Alitalo et al.

Application No.: 10/774,802

Confirmation No.: 9059

Filed: February 9, 2004

Art Unit: 1647

For: Therapy Targeting FLT4 (VEGFR-3) Expressed  
in Blood Vessels

Examiner: Ian Dang

**APPLICATION FOR PATENT TERM  
ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Madam:

The Applicants request that the U.S. Patent and Trademark Office (PTO) reconsider its calculation of Patent Term Adjustment (PTA) for the above-referenced application. This request is timely filed after issuance of a Notice of Allowance and prior to payment of the issue fee.

The fee of \$200.00 required under 37 C.F.R. § 1.18(e) has been paid by credit card. The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed, or which should have been filed herewith to our Deposit Account No. 13-2855, under Order No. 28967/34891.1.

## **I. INTRODUCTION**

"A Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. "B Delays" are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than a three year application pendency.

## **II. REQUEST FOR RECONSIDERATION AND INCREASE IN THE PTO'S CALCULATION OF "A DELAY"**

As set forth below, the PTA was miscalculated to the detriment of the Applicants because the wrong action was selected as the first action.

### **A. Authorities that define "A delay."**

The statute and rules that govern "A delay" are set forth in 35 USC §154(b)(1)(A) and 37 CFR §1.702(a).

### **B. Proper calculation of "A Delay" for the eventual patent based on the present application.**

The Office calculated "A" delay at the time of allowance to be 576 days, broken down as follows:

(i) 496 days until mailing of a restriction requirement on 08-18-2006 (more than 14 months after the filing date);

(ii) 78 days between a response dated 3-23-07 and an action dated 10-09-07; and

(iii) 2 days between an amendment dated 02-11-08 and an action dated 06-13-08.<sup>1</sup>

These calculations appear to be accurate, *assuming* that the action dates were correctly selected for making the calculations. However, during prosecution the Applicants successfully petitioned to have the restriction requirement

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<sup>1</sup> The (iii) 2 day period above should probably be recalculated as 30 days due to the necessity to clarify the status of certain claims in an interview, that were not addressed in the action. (See interview summary dated 07-11-2008.) However, as detailed below, this portion of "A" delay overlaps with "B Delay" and adjustment of the "A delay" for this period does not appear to affect the penultimate PTA calculation.

withdrawn. (See petition dated 3-22-2007 and decision granting petition dated 05-23-2007.) Thus, for purposes of 37 CFR 1.702(a)(1), the PTO is using an action that was *withdrawn* as the first action. Because the restriction requirement was withdrawn, the Applicants request that the first action, for purposes of PTA, be considered to be the action dated 11-20-2006, i.e., the first action that was not withdrawn by the PTO. On this basis, the first action was not issued until 14 months plus **590 days** after the filing date; and the total “A” delay should be 670 days.

### **III. THE PTO FAILED TO CALCULATE "B DELAY" TO THE DETRIMENT OF THE APPLICANTS**

The PTO concluded that if the patent based on this application were to issue on the Tuesday before the date that is 28 weeks after the mailing of the Notice of Allowance, then PTA would only be 512 days. In making this determination, the PTO did not apply the proper standard for determining the period of "B Delay" under 35 U.S.C. § 154(b)(1)(B). The PTO accorded no PTA for “B Delay.”

#### **A. Authorities that define “B Delay”**

The statute provides, in relevant part, that the term of a patent shall be extended if the PTO fails to issue a patent within three years after the "actual filing date" of the application. See 35 U.S.C. § 154(b)(1)(B). The relevant PTO rules are set forth in 37 CFR 1.702(b)

#### **B. Proper calculation of “B Delay” for the eventual patent based on the present application.**

The actual filing date of the present application for calculating PTA is February 9, 2004. The period beginning on February 10, 2007 (the day after the date that is three years after February 9, 2004, the filing date of the present application), and ending on the Office’s projected issue date (July 6, 2010, i.e., 28 weeks from the mailing date of the Notice of Allowance on December 22, 2009) should be credited to the Applicants as “B Delay”. That “B Delay” period is approximately **1,243 days**.

The PTO’s calculation of PTA made no provision for this “B Delay” and thus is plainly incorrect.

#### IV. OVERLAP OF “A DELAY” AND “B DELAY”

In *Wyeth v. Dudas*, (D.DC, CA No. 07-1492, Mem. Op. September 30, 2008), *aff'd*, *Wyeth v. Kappos*, Appeal No. 2009-1120 (Fed. Cir. Jan. 7, 2010), the Office’s reviewing courts have construed the statutory provision governing overlap to mean that (a) overlap of the “A Delay” and the “B Delay” occurs when the “A Delay” and “B Delay” occur on the same calendar day, and that (b) “B Delay” does not begin until three years after the actual filing date.

In this case, the “B Delay” did not begin until February 10, 2007.

According to Applicant’s request above, **670 days** of “A Delay” accumulated before issuance of the notice of allowance, of which **590 days** do not overlap with the “B delay” that began accruing on February 10, 2007. (80 days of “A Delay” occurred during the overlap period (February 10, 2007 through December 22, 2009).

According to Office’s calculations, **576 days** of “A Delay” accumulated before issuance of the notice of allowance, of which **496 days** do not overlap with the “B delay” that began accruing on February 10, 2007. (80 days of “A Delay” occurred during the overlap period (February 10, 2007 through December 22, 2009).

#### V. APPLICANT DELAY

The Applicants do not dispute, for purposes of this request, the PTO’s calculation of **64 days** constituting a failure to engage in reasonable efforts to conclude processing or examination of the application as set forth in 37 C.F.R. § 1.704.

#### VI. CONCLUSION – CORRECT PATENT TERM ADJUSTMENT

Because the PTO miscalculated “A delay” and failed to calculate, or miscalculated “B Delay,” the PTO’s PTA calculation of **512 days** is incorrect. As such, the Applicants respectfully request reconsideration of the PTA in the following manner.

$$[\text{A delay} + \text{B delay}] - \text{Overlap} - \text{Applicant delay} = \text{PTA}$$

If “A delay” is recalculated as requested above, then **[A delay + B delay] = 1913** and total PTA should be **1769 days**:

If “A delay” is calculated as specified in the Notice of Allowance, then **[A delay + B delay] = 1819** and total PTA should be **1675 days**:

These calculations presume an issue date of 07-06-2010 as projected in the Notice of Allowance.

Dated: January 28, 2010

Respectfully submitted,

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